

Danila B. Oder
530 South Kingsley Drive, #402
Los Angeles, California 90020-3536
(213) 387-5122 doder@hsc.usc.edu

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Dockets Management Branch (HFA-305)
Food And Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 98N0339
Docket No. 98N1265

To whom it may concern:

I wish to register my objections to provisions of the Memorandum of Understanding (MOU) as published by the FDA on January 21, 1999. The restrictions the MOU places on compounding pharmacies have the effect of denying many citizens the option of using natural, as opposed to synthetic products. The MOU also may jeopardize my ability to buy the products I choose from the pharmacists I choose.

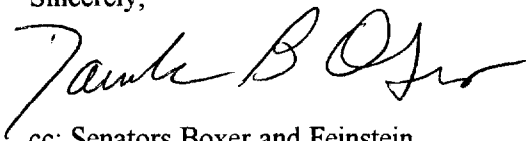
In particular, I refer to sections MOU II-C and III-C: Distribution of Inordinate Amounts of Compounded Drugs. By placing restrictions on the amounts that can be sold out of state, these provisions discriminate against consumers who do not live in the state where the products preferred by their physicians are compounded. As a Californian, I am quite aware that California is the national center for alternative medicine. Residents of states that do not have the same concentration of expertise and products will be unable to acquire the health care they and their doctor choose. Federal restrictions in place effectively deny these products to the vast majority of consumers.

Section II-B of the MOU refers to restrictions on a compounding pharmacy's right to promote its products and services. The result is that most consumers don't know they exist, and the only physicians who know about them have sought them out--a difficult task in this era of information overload and physician overscheduling.

In contrast, FDA does not prevent manufacturers of patented, synthetic, one-size-fits-all preparations from intense, multi-targeted advertising designed to persuade consumers to tell their physicians to prescribe their drugs. I work in a hospital and I see this kind of consumer-directed advertising daily: on give-aways, in medical journals, in *Reader's Digest* and other magazines. Even the news media are constantly leaked stories about this or that new wonder drug. Remember phen-fen?

Please amend the memorandum of understanding to avoid jeopardizing my right to buy products compounded for my needs anywhere I choose in the United States. I want there to be no restrictions on the delivery of a compounded medication prescribed for me, regardless of where I live or travel.

Sincerely,

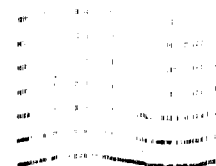
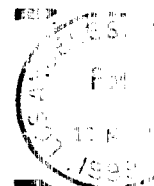


cc: Senators Boxer and Feinstein

98N-1265

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